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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,969	12/14/2001	Richard A. Pittner	0401-UTL-0	7314
28381	7590	07/26/2006	EXAMINER	
ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			LI, RUIXIANG	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 07/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/016,969	Applicant(s) PITTNER ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/17/2006 & 03/30/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,43-47,51 and 54-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,43-47,51 and 54-74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/1/06, 5/9/06, 2/2/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The supplemental response filed on 05/17/2006 and the response filed on 03/30/2006 have been entered. Claims 33, 43-47, 51, and 54-74 are pending and under consideration. It is noted that there are two claims that are numbered as claim 72. Thus, the second claim 72 is renumbered as claim 73, whereas the original claim 73 is renumbered as claim 74 (See 37 CFR 1.126).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Withdrawn Objections and/or Rejections

The rejections of claims 1, 8, 34-42, 48-50, 52, and 53 under 35 U.S.C. 112, first paragraph, for scope of enablement and written description have been withdrawn in view of canceled and amended claims.

The rejection of claims 1, 8, 33-51, 54, and 56-63 under 35 U.S.C. 112, second paragraph, has been withdrawn in view of canceled and amended claims.

The rejection of claims 1, 8, 34-42, 48, 49, 52, 53, and 55 under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992) has been withdrawn in view of amended and cancelled claims.

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The rejection of claims 1, 8, 33-42, 47-50, and 52-62 under 35 U.S.C. 102(b) as being anticipated by Okada et al. (*The Endocrine Society 75th Annual Meeting Program & Abstract*, page 180, Abstract 520B, 1993) has been withdrawn in view of amended and cancelled claims.

The rejection of claims 44, 46, and 63 under 35 U.S.C. 103(a) as being unpatentable over Okada et al. (*The Endocrine Society 75th Annual Meeting Program & Abstract*, page 180, Abstract 520B, 1993) has been withdrawn in view of amended claims.

The rejection of claim 51 under 35 U.S.C. 103(a) as being unpatentable over Okada et al., as applied to claims 1, 8, 33-42, 47-50, and 52-62, in view of Naslund et al. (Int. J. Obes. Relat. Metab. Disord. 23:304-311, 1999) has been withdrawn in view of the amended claims, from which claim 52 depend.

The objection to claims 8, 34-36, 43-46, and 56-58 because of the recitation of "peripheral parental" has been withdrawn in view of either canceled or amended claims.

Information Disclosure Statement

The information disclosure statements filed on 06/01/2006, 05/09/2006, and 02/02/2006 have been considered by the Examiner and a signed copy has been attached to this office action.

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Claim Rejections under 35 USC § 112, 1st paragraph

The rejection of claims 33, 43-46, 51, 54-63 under 35 U.S.C. 112, first paragraph, for scope of enablement is maintained. New claims 64-74 are also rejected on the same basis. Claims 33, 43-46, 51, 54-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method comprising peripherally administering an effective amount of a PYY or PYY(3-36) to a human subject, does not reasonably provide enablement for methods of administering a genus of PYY agonist analogs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with the claims.

Applicants argue that the specification lists several additional agonists of Y receptors in Table 1, including NPY, NPY3-36, PP, and Ac-PYY[22-26]. This is not found to be persuasive for the following reasons. First, it is clearly on the record of the prosecution of this case that NPY and PP are not considered by Applicants to be PYY agonists of the present invention (see Applicants' remarks submitted on 10/07/2002. Secondly, the limitation recite in the instant claims excludes NPY as an agonist of PYY because NPY comprises YP as first two amino acids in the N-terminal. Moreover, the specification discloses that NPY, NPY[3-36], PP, and Ac-PYY[22-36] are not active in reducing food intake in overnight-fasted NIH/SW mice (Example 1) and gastric emptying in HSD rats (Example 2).

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Applicants argue that the prior art teaches PYY agonists and the references are incorporated into the specification. This is not found to be persuasive because the references do not teach the PYY agonist analogs in the context of reducing nutrient availability, food intake or body weight and do not teach how to identify a PYY agonist analog recited in the instant claims.

Applicants argue that the claims have been amended to recite only those PYY agonist analogs which bind a subset of Y-receptors to elicit a specific subset of pharmacological responses. This is not found to be persuasive because what Applicants are arguing is not the same as the limitation recited in the claims. Moreover, the limitation of “wherein the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor” does not provide a definitive functional limitation for the PYY agonist analogs because it involves two varying factors: the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor. Thus, the specification does not provide sufficient guidance and/or working examples on how to make the genus of PYY agonist analogs and thus how to use the instantly claimed invention.

Applicants argue that Applicants have amended the claims to include a structural limitation, such that the PYY agonist is a peptide analog of PYY which does not comprise YP as its first two consecutive N-terminal amino acids. This is not found to be persuasive because such a limitation merely excludes PY from the amino acid

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sequence of PYY agonist analogs, but does not indicate what conserved structure the PYY agonist analogs have.

Claim Rejections under 35 USC § 112, 1st paragraph, Written Description

(i). The rejection of claims 33, 43-46, 51, 54-63 under 35 U.S.C. 112, first paragraph, for written description is maintained. New claims 64-74 are also rejected on the same basis.

Applicants argue that PYY agonists are adequately described in the specification and several were known in the art at the time of filing and were incorporated by references. Similarly, description is provided for the administration of a PYY or PYY agonist with a GLP-1, an exendin, an amylin, a leptin, their agonists, or any combination thereof, as provided in claim 51. This is not found to be persuasive for the reasons provided in paper No. 11172005 (mailed on 11/23/2005).

Applicants argue that Applicants have further defined the genus of PYY agonists to include those PYY agonists which are peptide analogs of PYY that do not comprise YP in the first two amino acid positions, and which elicit a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[3-36] at a Y1 receptor. Applicants argue that the amendment to the claims have provided sufficient structural description of the genus of PYY agonist analogs, including disclosure of additional distinguishing identifying characteristic of PYY agonist analogs, and the rejection is overcome.

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Applicants' argument has been fully considered, but is not deemed to be persuasive for the following reasons. The amended claims and newly added claims are drawn to methods comprising peripherally administering to a human subject a PYY agonist analog, wherein the PYY agonist analog is a peptide which does not comprise YP as its first two consecutive N-terminal amino acids, wherein the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor. The specification defines "PYY agonist analogs" as any compound structurally similar to a PYY that have a PYY activity typically by virtue of binding to or otherwise directly or indirectly interacting with a PYY receptor or other receptors with which PYY itself may interact to elicit a biological response (the 2nd paragraph of page 6). The limitation of "PYY agonist analog is a peptide which does not comprise YP as its first two consecutive N-terminal amino acids" does not provide a structural feature of the recited PYY agonist analogs because it merely excludes PY from the amino acid sequence of PYY agonist analogs, but does not indicate what structure the PYY agonist analogs have. Moreover, the limitation of "wherein the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor" does not provide a definitive functional limitation for the PYY agonist analogs because it involves two varying factors: the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor. Thus, the amended claims and newly added are drawn to a method comprising administration of a genus of structurally undefined peptide PYY agonist analogs.

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(ii). Claim 73 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New claim 73 recites a limitation “wherein the pharmacological effect at the Y1 receptor is an increase in blood pressure”, which introduces new matter. There is no sufficient support for the limitation at page 21 (lines 10-12) as pointed out by Applicants.

Claim Rejections under 35 USC § 112, 2nd paragraph

Claims 33, 43-47, 51, 54-72, and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 33, 43-47, 51, 54-72, and 74 are indefinite because they recite a limitation, “wherein the PYY agonist analog elicits a pharmacological effect at a Y2, Y5, or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor”. First of all, the limitation is not unambiguously defined because the comparison involves two varying factors: the PYY agonist analog elicits a pharmacological effect at a Y2, Y5 or Y7 receptor greater than that of PYY[1-36] at a Y1 receptor. Secondly, neither the specification nor the art define the term “a pharmacological effect” unambiguously, rendering the claims indefinite.

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Claim 74 is indefinite because they recite "PP". It is suggested that "PP" be spelled out in the claim.

Claim Rejections Under 35 U. S. C. § 102 (b)

The rejection of claims 33, 47, 54, 56-60, and 62 under 35 U.S.C. 102(b) as being anticipated by Yoshinaga et al. (*Am. J. Physiol.* 263:G695-701, 1992) is maintained. New claims 64, 71, 72, and 74 are also rejected on the same basis set forth in Paper No. 11172005 (mailed on 11/23/2005).

Applicants argue that Yoshinaga et al. teach that administration of PYY and PYY(3-36) to dogs inhibits pancreatic exocrine and gastric acid output. Yoshinaga et al. does not teach or suggest reducing food intake, nutrient availability, caloric efficiency or appetite, nor reducing weight, weight gain or increasing weight loss. Furthermore, Yoshinaga does not teach the claimed subject populations, i.e., human subjects, subject in need, or subjects having a condition or disorder which can be treated by reducing caloric efficiency, nutrient availability, food intake, appetite, body weight or body weight gain, or increasing weight loss. Thus, Yoshinaga does not teach, expressly or inherently, each element recited in the claims, and the 102(b) rejections is improper.

Applicants' argument has been fully considered, but is not deemed to be persuasive because Yoshinaga et al. teach a method of inhibiting pancreatic exocrine and gastric acid output, which are necessarily linked to other properties of PYY or PYY agonists, such as caloric efficiency, nutrient availability, appetite, food intake, or weight (see

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bottom of the instant specification). Moreover, since Yoshinaga et al. teach a method of administering to a subject the same agent (PYY agonist analog, PYY(3-36)) in the same dose as that of the instantly claimed method, the intended uses and properties of the PYY agonist analog (PYY(3-36)) recited in the claims are inherent to the method taught by Yoshinaga et al. The property or functional activity is inherent to the structure of a molecule because it is well established that a property or function of a molecule depends upon its structure. It is noted that recognition by a person of ordinary skill in the art is not required to show anticipation by inherency (*Schering Corp. v. Geneva Pharmaceuticals, Inc.*, No. 02-1540 (Fed. Cir. Aug. 1, 2003)).

Claim Objections—Minor Informalities

Claim 73 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. In all claims from which claim 74 depend, a limitation “ which does not comprise YP as its first two consecutive N-terminal amino acids” is recited, and such a limitation already exclude PP as a PYY agonist analog.

Conclusion

No claims are allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

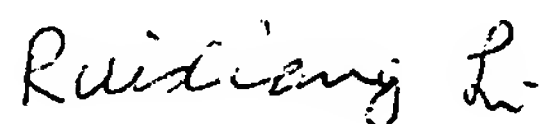
Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.
Primary Examiner
July 23, 2006

RUIXIANG LI, PH.D.
PRIMARY EXAMINER